

OPERATIONALIZING THE 2020 ANTI-KICKBACK STATUTE, CIVIL MONETARY PENALTY LAW, AND STARK LAW FINAL RULES

Health Ethics Trust

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Purpose and Agenda

- Overview of AKS, Stark Law, and CMPL
- Selected Key Provisions of 2020 Final Rules
- Issue Spotting & Mitigating Risk

OVERVIEW – AKS, STARK LAW, AND CMPL

Regulatory Background

Federal Healthcare Laws

Stark/Self-Referral Law

Only Physician Relationships

Anti-Kickback Statute

All Healthcare Relationships

Regulatory Equation



Regulatory Definitions – Healthcare Provider



Physician

Nurse
Practitioner

Physician
Assistant

Home
Health
Agency

Therapy
Company

Regulatory Definitions: Anything of Value

Anything of Value

Monetary:

- Payment for Professional Services
- Payment to Medical Director
- Payment for Consulting Services
- Investment Opportunity
- Opportunity for Business
- Cost Sharing Reductions

Non-Monetary:

- Meals
- Travel
- Gifts
- Use of Space
- Continuing Medical Education Support
- Support Staff
- Electronic Medical Records

Antikickback Statute

- Prohibits knowingly and willfully offering, paying, soliciting or receiving remuneration (i.e., anything of value) to induce referrals or generate Federal health care program business
- Remuneration includes discounts, gifts, supplies, free staff, equipment or any other item of value

Antikickback Statute

- Violation may be found if one purpose is to induce referrals, even if there are other legitimate purposes for the payment
- Broad scope of the statute
 - Regulatory safe harbors
 - Statutory exceptions
- May result in civil, administrative, and/or criminal penalties, damages, etc.

Physician Self-Referral/Stark Law

- Prohibits Medicare* payment for Designated Health Services (DHS) if physician referring DHS has:
 - (i) an ownership or investment interest, or
 - (ii) a compensation arrangementwith the entity submitting the claims for the DHS.
- DHS includes, among others:
 - Clinical laboratory services
 - PT and OT services
 - Radiology and radiation therapy services
 - Inpatient and outpatient hospital services

Physician Self-Referral/Stark Law

- Common regulatory exceptions address space and equipment rentals, employment relationships, personal services arrangements, and fair market value compensation
- Strict liability
- Civil and administrative enforcement – prohibition against claims submission and payment
- Compliance with an exception is mandatory

CMPL - Beneficiary Inducement

- Addresses remuneration to a Medicare or Medicaid beneficiary to influence or steer them to a particular provider
- Prohibits offering remuneration if offeror knows or should know that the remuneration is likely to influence the beneficiary's selection of a health care provider for items or services for which payment may be made by Medicare/Medicaid
- Like AKS, "remuneration" is broadly defined, but there are exceptions

SELECTED KEY
PROVISIONS OF 2020
FINAL RULES

Selected Key Provisions of 2020 Rules

CMS Stark Final Rule

- Value-based care
- Non-monetary donations of cybersecurity technology
- Revisions - Directed Referrals
- Revised definitions – e.g., commercially reasonable; volume/value; fair market value

OIG AKS Final Rule

- Value-based arrangements
- Non-monetary donations of cybersecurity technology
- Patient engagement and support
- PSA Safe Harbor and outcomes-based payments
- Bundled warranty arrangements

Value-Based Arrangements

- OIG Final Rules include new AKS safe harbors to protect remuneration exchanged between or among eligible participants in a “value-based arrangement”
- In order to qualify for any of these safe harbors, there needs to be a Value-Based Enterprise (VBE)

Value-Based Arrangements

- VBE means two or more VBE participants:
 - Collaborating to achieve at least one value-based purpose;
 - Each of which is a party to a value-based arrangement with the other;
 - Have an accountable body/person responsible for financial and operational oversight; and
 - Have a governing document that describes the VBE and how it is intended to achieve its value-based purpose

Patient Engagement and Support Safe Harbor

- *NEW Safe Harbor* protects **in-kind** remuneration furnished in connection with a value-based arrangement
- Remuneration furnished by a VBE participant (or an eligible third-party agent) directly to a patient in a target patient population
- Patient Engagement and Support directly connected to the coordination and management of care of the target patient population

Patient Engagement and Support Safe Harbor

- Recommended by the patient's licensed healthcare provider and advances one or more enumerated clinical goals (*e.g.*, adherence to a treatment regimen)
- Aggregate retail value cannot exceed \$500 per patient per year (adjusted for inflation)

Additional Limitations

- Only VBE Participants and TPPs: Safe harbor only applies to VBE participants and only protects remuneration provided to a patient in a defined target patient population.
- Ineligible Participants: Certain entities, such as pharmaceutical manufacturers/distributors, laboratories, and DMEPOS suppliers, are ineligible, i.e., they cannot be VBE participants or otherwise fund or furnish the remuneration.

Additional Limitations

- Marketing Restrictions: VBE participant cannot use the patient engagement tools or support to market other reimbursable items or services or for patient recruitment purposes.
- Insurance Coverage Status of the Patient: Availability of patient engagement tool or support cannot be determined in a manner that takes into account the type of insurance coverage the patient has

Examples

OIG provided examples of tools and support that could be structured to fit in the safe harbor:

- Transportation support:
 - Provision of in-kind transportation, such as transit or rideshare vouchers organized by the VBE participant
 - Vehicle modifications

Examples

- Housing/infrastructure support:
 - Home modifications such as grab bars, air filters or purifiers, and other modifications that allow patients to live safely at home
 - Temporary housing for an individual experiencing homelessness or living far from a hospital following a surgical discharge
 - Providing broadband access to a patient to enable remote patient monitoring or virtual care

Examples

- Nutrition and exercise support:
 - Grocery or meal delivery services, nutrition supplements, and nutrition education
 - Exercise or fitness programs or equipment
- Behavioral health supports:
 - Incentives as part of addiction recovery programs, including peer-to-peer programs and contingency management programs
 - Incentives as part of mental health programs
 - Supports related to interpersonal violence

Examples

- Unlikely to fit in the safe harbor:
 - Tools and supports related to finding employment
 - Routine or ongoing rent or utility payments.

Directed Referrals

- Revisions to existing Stark Law exception, but has renewed interest in utilizing exception
- Traditionally, applied under employment, personal services, and managed care exceptions
- Revisions clarified affirmative requirement to comply with requirements of exception in the context of directed referrals in other exceptions related to physician compensation relationships, such as academic medical centers; group practice arrangements with a hospital; fair market value compensation; and indirect compensation arrangements.

Directed Referrals

- Other (existing) requirements of the exception are:
 - Physician compensation/compensation formula is set in advance for the duration of the arrangement (and any changes must be made only on a prospective basis)
 - Physician compensation is consistent with fair market value

Directed Referrals

- Existing requirements also include:
 - Physician compensation is not contingent on the number or value of the physician's in-network referrals
 - The requirement to make in-network referrals is set out in writing* and signed by both the physician and system
 - Required referrals related solely to services covered by the physician arrangement and are reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement

Directed Referrals

- The following exceptions apply:
 - Where a patient expresses a preference for a provider outside of the network;
 - Where a patient's insurer determines the provider;
 - Where in the physician's judgment an in-network referral is not in the patient's best medical interests

Nonmonetary Donations of Cybersecurity Technology – CMS and OIG

- New safe harbor to protect donations of cybersecurity technology and services “necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity.”
- Requires written agreement signed by the parties
- Donor does not take into account volume or value of referrals or of other business generated between the parties
- Donor cannot condition donation on future referrals
- Recipient cannot make receipt of cybersecurity technology or services a condition of doing business with donor
- Donor does not shift costs of cybersecurity technology or services to any Federal health care program

CMS – New Definitions

- Establishes bright-line rule that compensation will be considered to take into account the volume or value of referrals or other business generated between the parties only when:
 - the mathematical formula used to calculate the amount of the compensation includes the referrals or other business generated as a variable, and the
 - amount of the compensation correlates with the number or value of the physician's referrals to or the physician's generation of other business for the entity.
- Defines “commercially reasonable” to mean the arrangement furthers a legitimate business purpose and is sensible, considering the characteristics of the parties (even if it does not result in profit for one or more parties.)

OIG Revisions to PSA Safe Harbor and New Outcomes-Based Payments Safe Harbor

- Increased flexibility for periodic, sporadic, or part-time arrangements by eliminating requirement that contract specify exact schedule, length, and charge
- Edits to clarify that the methodology for determining compensation is set in advance, consistent with FMV, and not determined in manner that takes into account volume or value of referrals or other business generated
- New safe harbor for outcomes-based payments – protects payments tied to achieving measurable outcomes that improve patient or population health or reduce payor costs (while maintaining or improving quality of care)
 - Certain entities are ineligible for the outcomes-based payment exception (e.g., pharma manufacturers, PBMs, labs, compounding pharmacies, device or medical supplier manufacturers, distributors, or wholesalers, DMEPOS sellers)

Bundled Warranties

- OIG modified the existing Warranties Safe Harbor as part of the 2020 AKS Final Rules as follows:
 - if a warranty covers more than one item or service, the items or services must be reimbursed by the same Federal health care program and “in the same Federal health care program payment.”
 - Contrast to the Discount Safe Harbor language on bundling, which references reimbursement by the “same Federal health care program using the same methodology.”
 - OIG also specified that a manufacturer or supplier could not condition a warranty on a buyer’s exclusive use of, or minimum purchase of, the manufacturer or supplier’s items or services.

ISSUE SPOTTING & MITIGATING RISK

Types of Arrangements

Service Arrangements

- Healthcare Provider
- Service/
Compensation

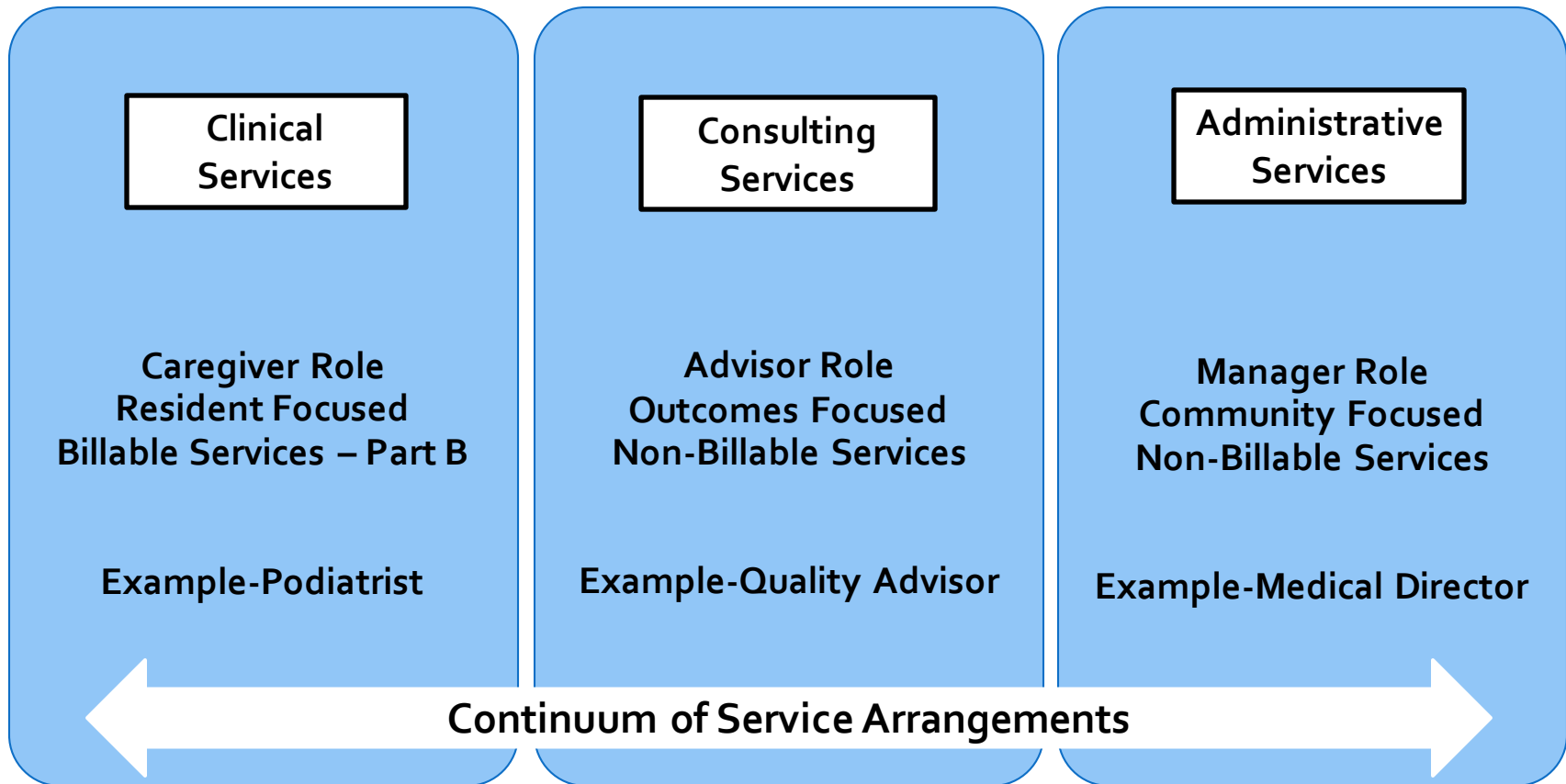
Space Arrangements

- Healthcare Provider
- Space/
Lease Payment

Access Arrangements

- Healthcare Provider
- Access/
No Payment

Types of Service Arrangements



Elements of a Contract

1. State the Purpose of Arrangement

2. Include Details of Arrangement

3. Part-Time Arrangements – Rule changes

4. Represent Reasonable & Necessary Arrangement

5. Explain the Business Need for Arrangement

6. Be Signed by Both Parties

Payment Must:

Reflect Fair Market Value (FMV)

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graph TD; A[Reflect Fair Market Value (FMV)] --> B[Be Set in Advance]; B --> C[Not Account for Volume or Value of Referrals]; C --> D[Not Account for Volume or Value of Business Generated];
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Be Set in Advance

Not Account for Volume or Value of Referrals

**Not Account for Volume or Value of Business
Generated**

Steps Toward Mitigating Risk

(1) Identify Arrangement

Type Arrangement

Reason for Arrangement

(2) Conduct FMV Analysis

Service Arrangements

Space Arrangements

(3) Document Arrangement in Writing

Service Agreement

Lease Agreement

Memorandum of Understanding

Hypothetical #1

- A hospital and a physician practice form a VBE to coordinate and manage care of diabetic patients whose income is below the federal poverty line.
- As part of the VBE, the hospital sets up and staffs a food bank at the physician practice that focuses on healthy food options.
- The practice makes the food bank available to patients in the target patient population and offers free food to these patients under the Patient Engagement and Support Safe Harbor.
- The practice tracks patients' receipt of these food items to ensure they do not receive more than \$500 per year in free food from the food bank.
- Alternative: The tracking proves harder than expected and many or most patients receive more than \$500 per year in free food.

Hypothetical #2

- Review hypothetical on separate handout
- Questions:
 1. Does this referral requirement comply with the Stark Law?
 2. Does this referral requirement comply with the AKS?
 3. What is your assessment of the level of risk under the AKS?
 4. What compliance safeguards should New Deal and/or Olds House implement to reduce that risk?

ADDITIONAL RESOURCES

Additional Resources

- CMS Fact Sheet, <https://www.cms.gov/newsroom/fact-sheets/modernizing-and-clarifying-physician-self-referral-regulations-final-rule-cms-1720-f> (11/20/2020)
- CMS Final Rule, <https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26140.pdf> (12/2/2020)

Additional Resources

- OIG Fact Sheet, <https://oig.hhs.gov/reports-and-publications/federal-register-notices/factsheet-rule-beneficiary-inducements.pdf> (11/20/2020)
- OIG Final Rule, <https://www.govinfo.gov/content/pkg/FR-2020-12-02/pdf/2020-26072.pdf> (12/2/2020)

Additional Resources

- Alston Health Care Advisory on Final Rule (11/25/2020)
<https://www.alston.com/en/insights/publications/2020/11/cms-and-oig-significantly-update>
- Alston Health Care Advisory on Proposed Rule (12/19/2019)
<https://www.alston.com/en/insights/publications/2019/12/cms-and-oig-release-proposed-rules>
- Article by Seema Verma & Kim Brandt, Updates to Stark Law Regulations Will Drive Value in the Health Care System (12/9/2020)
<https://www.healthaffairs.org/doi/10.1377/hblog20201208.472326/full/>

Questions?

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